DMB

Display Date 1-21-00
Publication Date 1-24-00
Certified SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0132]

FDA Modernization Act of 1997; Guidance on Medical Device Tracking; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance document entitled ''Guidance on Medical Device Tracking.'' This guidance document, which replaces the previous guidance issued on February 12, 1999, provides guidelines to manufacturers and distributors concerning their responsibilities for medical device tracking under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance on Medical Device Tracking'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on ''Guidance on Medical Device Tracking'' to the contact person (address below). See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

NAD 3

I. Background

Section 211 of FDAMA (Public Law 105–115) amended the tracking provisions of section 519(e) of the act (21 U.S.C. 360i(e)) to authorize FDA, at its discretion, to issue orders that require a manufacturer to track a class II or class III device if: (1) The failure of the device would be reasonably likely to have serious adverse health consequences; (2) the device is intended to be implanted in the body for more than 1 year; or (3) the device is life sustaining or life supporting and used outside a device user facility. The FDAMA tracking provisions became effective on February 19, 1998.

The revised final guidance replaces the February 1999 guidance and clarifies the devices that must be tracked. Agency experience indicates that industry and other interested parties are confused about the term ''replacement heart valves'' because there is more than one type. The category of replacement heart valves that must be tracked is limited to mechanical heart valves only and does not include human allograft (tissue) heart valves. The revised guidance document includes this descriptive limitation.

Agency experience also indicates that industry and other interested parties are confused about which infusion pumps are subject to medical device tracking because the types of fluids the pumps are intended to deliver may not be clear from indications for use set out in labeling. The previous guidance stated that infusion pumps, except those designated and labeled for use exclusively for fluids with low potential risks, such as enteral feeding or anti-infectives, were subject to tracking. The agency has reevaluated the types of infusion pumps subject to tracking and the best way to describe them in the guidance document. The revised guidance explains that tracking is required only for electromechanical infusion pumps that are used outside a user facility. This was the agency's position in 1993 when tracking was originally implemented (58 FR 43442 at 43449). The phrase ''electromechanical only'' will be used to describe the pumps rather than a reference to the classification regulation. FDA believes this will clarify the guidance because the terms used in the classification language for infusion pumps may include types that do not require tracking.

Finally, the agency added abdominal aortic aneurysm stent grafts to the devices that must be tracked. The agency issued tracking orders for these devices on September 28, 1999, which were effective immediately. FDA determined that these devices meet the statutory tracking criteria under section 519(e) of the act because failure of the device would be reasonably likely to have serious adverse health effects. The agency may add or remove devices from the list of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance, or other information.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical device tracking requirements, as amended by FDAMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 2 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on Medical Device Tracking'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (169) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated

on a regular basis, the CDRH home page includes ''Guidance on Medical Device Tracking,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Medical Device Tracking'' will be available at http://www.fda.gov/cdrh/ochome.html.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance.

Dated: 1/9/00

January 9, 2000

Linda D. Kahan

Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Lynette N. Reese